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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,242	10/15/2001	Olga Bandman	PF-0451-2 DIV	4454

27904 7590 12/04/2003

INCYTE CORPORATION (formerly known as Incyte Genomics, Inc.)
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,242	BANDMAN ET AL.	
	Examiner	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 9-10 and 56, drawn to isolated polypeptide (SEQ ID No. 1), classified in class 530, subclass 350.

II. Claims 3-7, 12-13 and 57, drawn to isolated polynucleotides, classified in class 536, subclass 23.1+.

III. Claim 8, drawn to transgenic organism, classified in class 800, subclass 2.

IV. Claims 11, 31, 37, 40, 42, 43, drawn to antibodies, classified in class 530, subclass 387.1+.

V. Claims 14-16, drawn to method detecting target polynucleotides using hybridizing assays, classified in class 435, subclass 6.

VI. Claims 17-19, drawn to compositions of polypeptide and methods of treating HNLP related disorders, classified in class 514, subclass 12.

VII. Claim 20, drawn to method screening for an agonist, classified in class 435, subclass 7.1+.

VIII. Claim 21-22, drawn to compositions containing an agonist and method of treating HNLP related disorder, classified in class 514, subclass 12+.

IX. Claim 23, drawn to screening method for antagonists, classified in class 435, subclass 7.23+.

X. Claims 24-25, drawn to compositions and methods of treating a HNLP related disorder using antagonist, classified in class 514, subclass 12+.

XI. Claim 26, drawn to method of screening for a compound that binds to SEQ ID NO. 1, classified in class 435, subclass 7.1+.

XII. Claim 27, drawn to method of screening for a compound that modulated that activity of polypeptide, classified in class 435, subclass 7.1+.

XIII. Claim 28, drawn to method for screening a compound for effectiveness in altering expression of a target polynucleotide, classified in class 435, subclass 6.

XIV. Claim 29, drawn to method of assessing toxicity using polynucleotides, classified in class 435, subclass 6.

XV. Claims 30, 32-35 and 41, drawn to composition and methods of diagnosing using an antibody, classified in class 435, subclass 7.21+.

XVI. Claim 36, drawn to methods of making polyclonal antibodies, classified in class 530, subclass 389.1+.

XVII. Claim 39, drawn to method of making monoclonal antibodies, classified in class 435, subclass 325+.

XIX. Claim 44, drawn to method of detecting polypeptide using antibody, classified in class 435, subclass 7.1+.

XX. Claims 46-55, drawn to arrays and methods of using them, classified in class 435, subclass 287.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are chemically and structurally different, have different modes of operation and can be used in materially different processes. For example, the polynucleotides of Group II can be used in hybridization assays, whereas the products of Groups I, III-IV and XX cannot. The protein of Group I can be used to make antibodies and in therapy, whereas the compounds of Groups II-IV and XX cannot. The antibodies of Group IV can be used in immunoassays, affinity purification etc, whereas the compounds of Groups I-III and XX cannot. The transgenic organism and the arrays are structurally and chemically different from polynucleotides, proteins and antibodies.

Inventions V-XIX are unrelated because the involves different processes and have different effects. The methods of Groups VI, VIII, and X are directed to treatments whereas the methods of the other Groups are not. The methods of these Groups are patentably distinct because they are directed to using chemically and structurally different reagents. The methods of Group XV is directed to diagnosis whereas the methods of the other Groups are not. The method of Groups V-VII, IX, XI-XIV and XVIII are directed to screening/detecting compounds whereas the methods of the other Groups are not. The methods of these Groups are patentably distinct because they are directed to using chemically and structurally different reagents. The methods of Group XVI and XVII are directed to making antibodies whereas the methods of the other

Groups are not. The method of Group XIX is directed to protein purification whereas the methods of the other Groups are not.

> Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

> Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone restriction requirement was not made in this application due to an explicit request by Incyte and their policy of not making elections in response to telephonic restriction requirements.

> Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh